



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/607,580 | 06/26/2003 | Roberto C. Beretta | 015445-9002-01 | 5786 |

23409 7590 03/21/2008
MICHAEL BEST & FRIEDRICH LLP
100 E WISCONSIN AVENUE
Suite 3300
MILWAUKEE, WI 53202

EXAMINER

HANLEY, SUSAN MARIE

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

03/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/607,580

Applicant(s)

BERETTA ET AL.

Examiner

SUSAN HANLEY

Art Unit

1651

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 18, 20-22, 24, 25, 27-32 and 34-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32 and 34-41 is/are allowed.
- 6) ☒ Claim(s) 17, 18, 20, 21, 30 and 31 is/are rejected.
- 7) ☒ Claim(s) 22, 24, 25 and 27-29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 12/31/07 has been entered.

Claims 17, 18, 20-22, 24, 25, 27-32 and 34-41 are under examination.

Withdrawal of Rejections

The rejections not explicitly restated below are withdrawn due to Applicant's response in the amendment filed 12/31/07.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Art Unit: 1651

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17, 18, 20, 21, 30 and 31 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 5, 6 and 11-13 of U.S. Patent No. 6,979,307. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1 and 11 of '307 are drawn to a system for preparing an autologous solid-fibrin web wherein the system comprises sealed primary and secondary containers. The sealed primary container comprises a separation medium that can be a gel, a float device or beads and the secondary container comprises a coagulant. The system also comprises a transfer means, such as a cannula. The specification of '307 defines a gel as one that is thixotropic, capable of density-gradient separation of the plasma and the blood cells. The location of the thixotropic gel and be the bottom of the primary container (col. 10, lines 1-32). Thus, '307 is a specie of the instant claims because '307 claims two containers separated by a thixotropic gel wherein the second container holds a coagulant. The instant claims have open transitional language ("comprising") which allows for the prior art device to comprise additional features that are not instantly claimed, such as a transfer means and pressurized containers. The disclosure by '307 of calcium coagulants (claims 3 and 12), anticipates instant claim 21. Claims 5 and 13 of '307 name therapeutic agents contained in the secondary container as in instant claims 30 and 31. Claim 4 of '307 claims the presence of an anti-coagulant in the first container, as in instant claim 18. The system of '307 is interpreted as device because the claim language of '307 is directed to describing an apparatus/device and not the method of using it. It is noted that the MPEP 804 notes that it is appropriate to use the specification as a dictionary for claim interpretation:

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In *re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In *re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in *Vogel* recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Claims 17, 18, 20 and 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7, 9 and 10 of copending Application No. 11/284,584. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 7 of '584 is drawn to a system for preparing an autologous solid-fibrin web wherein the system comprises sealed primary and secondary containers. The sealed primary container comprises a separation medium that can be a gel, a float device or beads and the secondary container comprises a coagulant. The specification of '584 defines a gel as one that is thixotropic, capable of density-gradient separation of the plasma and the blood cells. The location of the thixotropic gel and be the bottom of the primary container (page 14, lines 1-15). Claim 7 of '584 also recites a transfer means. Thus, '584 is a specie of the instant claims because '584 claims two containers separated by a thixotropic gel wherein the second container holds a coagulant. The instant claims have open transitional language ("comprising") which allows for the

Art Unit: 1651

prior art device to comprise additional features that are not instantly claimed, such as a transfer means. The disclosure by '584 of calcium coagulants (claim 9), anticipates instant claim 21. Claim 10 of '584 claims the presence of an anti-coagulant in the first container, as in instant claim 18. The system of '584 is interpreted as device because the claim language of '584 is directed to describing an apparatus/device and not the method of using it. It is noted that the MPEP 804 notes that it is appropriate to use the specification as a dictionary for claim interpretation *supra*.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

Claims 22, 24, 25 and 27-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/
Examiner, Art Unit 1651

/Sandra Saucier/
Primary Examiner, Art Unit 1651